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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,297	03/01/2005	Takeshi Matsuda	10921.0288USWO	6278

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Minneapolis, MN 55402-0902

EXAMINER
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WHITE, DENNIS MICHAEL

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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09/25/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,297	<b>Applicant(s)</b> MATSUDA ET AL.	
	<b>Examiner</b> DENNIS M. WHITE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-7 and 9-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/12/2009 has been entered. Claims 1 and 13 are amended. Currently claims 1, 3, 5-7, and 9-18 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 3, 5-7, 9-10, 13, 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al (USP 5,527,509) and in view of Ray et al (USP 6,258,045).

Regarding claims 1, 3, and 5-7, Gibson et al teach a colorimetric enzymatic analytical test element ("test kit") comprising a plurality of reaction zones incorporating a dried enzyme composition, dyestuff, and reagent for colorimetric analysis ("penetration layer"), and a Cyclopore membrane ("pores have a size of 0.1-12  $\mu\text{m}$ " "porosity of 4-20 vol %" "formed by track etching") overlies the zone ("a plurality of coloration pads held in contact with the penetration layer" "a penetration membrane which are formed with a plurality of thicknesswise extending pores"), wherein a liquid sample is applied to the membrane and allowed to penetrate to the zone ("supplied to the penetration layer is

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fed to each of the coloration pads through the penetration layer” and “wherein the penetration layer is formed with a plurality of thicknesswise extending pores for allowing the sample liquid to penetrate thicknesswise of the penetration layer while preventing the sample liquid from spreading in a planar direction of the penetration layer”) (Figure 10: 15 and 16, col. 8 lines 7-23). Gibson is silent about wherein the penetration layer is laminated on a water absorbent carrier that spreads the sample liquid in the planar direction of the water absorbent carrier for drawing up by the penetration layer, the plurality of coloration pads being laminated on a surface of the penetration layer facing away from the water absorbent carrier for exposure on the penetration layer and the water absorbent carrier includes a laminated portion covered by the penetration layer and a sample applying portion extending beyond the penetration layer for exposure to apply the liquid sample.

Ray et al teach a biological collection device comprising an application member 114 (“water absorbent carrier”) facing a separation member 118 (“penetration layer is laminated on a water absorbent carrier that spreads the sample liquid in the planar direction of the water absorbent carrier for drawing up by the penetration layer”) (Fig. 4I) that can be track etched Cyclopore membrane material (col. 12 lines 40-45). The application member has a portion not facing the separation member (“water absorbent carrier includes a laminated portion covered by the penetration layer and a sample applying portion extending beyond the penetration layer for exposure to apply the liquid sample”) (Fig. 4I). Ray et al teach it is desirable to provide an application member (“absorbent carrier”) to the separation member (“penetration membrane”) because it is

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used as a target for placing, evenly spreading, and absorbing sample 72 (col. 17 lines 3-4).

Therefore it would have been obvious to one of ordinary skill in the art, as motivated by Ray et al to provide the application member ("water absorbent carrier") over the Cyclopore membrane of Gibson because it allows the sample to be evenly spread when it contacts the track etched membrane.

Regarding claim 9, Gibson/Ray teach the reaction zones are disposed in spaced relation along the strip ("wherein the plurality of coloration pads are arranged in a matrix") (Figure 9:16, col. 2 lines 28-30).

Regarding claim 10, Gibson/Ray et al teach the selection of appropriate dyestuffs may allow different colours to be displayed ("at least two of the plurality of coloration pads differ from each other with respect to coloration components for allowing measurement of a plurality of items") (col. 2 lines 31-34).

Regarding claim 13, Gibson et al teach a method for producing a test kit, comprising: printing reagents to the support which incorporate a dried enzyme composition and dyestuff ("a first step of forming a plurality of coloration pads by coating a carrier with a reagent liquid containing a coloration component using a non-contact dispenser and by thereafter drying the reagent liquid"); and applying a membrane to the reaction zone, wherein the sample liquid is applied to the membrane and allowed to penetrate to the reaction zone ("the plurality of coloration pads being exposed on the penetration layer" "wherein the penetration layer is formed with a plurality of thicknesswise extending pores for allowing the sample liquid to penetrate thicknesswise

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of the penetration layer while preventing the sample liquid from spreading in a planar direction of the penetration layer”) (col. 8 lines 7-23). Gibson is silent about forming a penetration membrane on a water absorbent carrier; wherein the water absorbent carrier spreads the sample liquid in the planar direction of the water absorbent carrier for drawing up by the penetration layer.

Ray et al teach method of producing a biological collection device comprising an application member 114 (“water absorbent carrier”) facing a separation member 118 (“penetration membrane on a water absorbent carrier”) (Fig. 4I) that can be track etched Cyclopore membrane material (col. 12 lines 40-45, Fig. 4I). Ray et al teach it is desirable to provide an application member (“absorbent carrier”) to the separation member (“penetration membrane”) because it is used as a target for placing, evenly spreading, and absorbing sample 72 (col. 17 lines 3-4) (“wherein the water absorbent carrier spreads the sample liquid in the planar direction of the water absorbent carrier for drawing up by the penetration layer”).

Therefore it would have been obvious to one of ordinary skill in the art, as motivated by Ray et al to provide the application member (“water absorbent carrier”) over the Cyclopore membrane of Gibson because it allows the sample to be evenly spread when it contacts the track etched membrane.

Regarding claim 15, Gibson/Ray teach the reaction zones are disposed in spaced relation along the strip (“wherein the plurality of coloration pads are formed in a matrix arrangement in the first step”) (Figure 9:16, col. 2 lines 28-30).

Regarding claim 16, Gibson/Ray teach the selection of appropriate dyestuffs may allow different colours to be displayed ("wherein, in the first step, at least two of the plurality of coloration pads differ from each other with respect to coloration components") (col. 2 lines 31-34).

4. Claims 11-12 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al (USP 5,527,509) in view of Ray et al (USP 6,258,045) and further in view of Iwata et al (US 2001/0028862)

Gibson/Ray teach the limitations of claims 1 and 13 as per above.

Regarding claims 11-12 and 17-18, Gibson et al teach apparatus and method of producing the device comprising the discs or reaction zone paper of 5 mm can be cut from the dried papers and mounted on the paper or card (col. 6 line 33). Gibson et al are silent about reaction zones or region ("the plurality of coloration pads") are formed within a specific region, and the surface area of the specific region is 2.0-15 mm x 2.0-15 mm and wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm<sup>2</sup>.

Iwata et al teach a test device and method of producing the device for a multi-items where in all the test papers for all items for one test are wetted by one shot dropping and transportation of a detecting part or a test device is not required upon measurement. The reaction zone for the horizontal line is preferably 8mm to 2cm and the vertical line is preferably 4 to 10mm. The diameter of the micro test papers ("coloration pads") is being 0.5 mm ("wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm<sup>2</sup>") (Para. 0082

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and 0084). It would have been desirable to have the dimensions of the total surface area of the reaction zone and the micro test papers ("coloration pads") within this range because having the micro test papers size too large, it becomes difficult to wet the test papers for the whole items by one shot dropping of the sample (Para. 0084).

Therefore it would have been obvious to one of ordinary skill in the art to provide Gibson et al device with the dimension of the surface area of the region of the reaction zones or region ("the plurality of coloration pads") within 2.0-15 mm x 2.0-15 mm and wherein the surface area of the specific region accounted for by the respective coloration pads is no more than 2.0 mm<sup>2</sup> because it provides the above advantages of one shot dropping of the sample.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gibson et al (USP 5,527,509) in view of Ray et al (USP 6,258,045) and further in view of Goerlach-Graw et al (USP 5,424,220).

Gibson/Ray teach the limitations of claim 13 as per above.

Regarding claim 14, Gibson et al teach the reagents are applied to the support by printing, for example screen printing and mask printing. Gibson et al are silent about the non-contact dispenser used in the first step is of an inkjet type.

Goerlach-Graw et al teach a analysis element comprising a chromatographic porous carrier, reaction zone, detection zone, and absorptive zones. The reagents can be applied with screen printing or ink-jet printing. It is desirable to use an ink-jet printing because it allows the application of smaller portions of reagent liquid.



Therefore it would have been obvious to one of ordinary skill in the art as motivated by Goerlach-Graw et al to use an ink-jet printer to print the reagents of Gibson et al in order allow the application of smaller portions of reagent liquid.

### ***Response to Arguments***

6. Applicant's arguments filed 8/12/2009 have been fully considered but they are not persuasive. Applicants argue that Gibson in view of Ray fails to teach the water absorbent carrier, penetration layer and coloration pads required by claims 1 and 13 nor a test kit that delivers sample in a manner set forth in claims 1 and 13. It is noted that Ray remedies the deficiency in Gibson of the application layer ("water absorbent layer") being in contact with the cyclospore membrane ("penetration layer") because it provides a layer that evenly spreads the sample when it contacts the track etched membrane. The combination of Gibson in view of Ray therefore teach the claimed limitations of claims 1 and 13.

### ***Conclusion***

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS M. WHITE whose telephone number is (571)270-3747. The examiner can normally be reached on Monday-Thursday, EST 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYLE A ALEXANDER/  
Primary Examiner, Art Unit 1797  
/dmw/